

Serial No. 09/912,957  
Filed: July 25, 2001

#### REMARKS

Claims 1, 2, 8, 10-15, 17, 18, 20-23, and 25-48 were pending in the subject application. Applicants have hereinabove amended claims 10, 20-23, and 29-31. Claims 1, 2, 8, 10-15, 17, 18, 20-23, 25-48 remain pending in the subject application.

Before addressing the substance of the Office Action, applicants point out that the above listing of claims is correct and the various listings of claims 1, 2, 8, 10-15, 17, 18, and 20-45 or 46 in the Office Action, omits claims 46 and/or 47 and 48, which have been pending since applicants' last amendment, and includes claim 24, which never was presented in this patent application.

Claims 20-23 and 29-31 were rejected under 35 U.S.C. § 112, second paragraph, as allegedly not having antecedent basis for the term "lipase inhibitor." Applicants have hereinabove amended these claims to reflect that the broader term "lipase inhibitor" has been narrowed to "orlistat." In view of applicants' amendments hereinabove, the rejection under 35 U.S.C. § 112, second paragraph, is moot. Reconsideration and withdrawal of the rejection is requested.

Claims 1, 2, 8, 10-15, 17, 18, and 20-46 were rejected under 35 U.S.C. § 103(a) as allegedly unpatentable in view of Gregg (U.S. Patent No. 5,883,109). Gregg is alleged by the Patent Office to disclose that bile acid sequestrants, such as cholestramine, colestipol and DEAE-Sephadex, and tetrahydrolipstatin (orlistat) are all useful as cholesterol lowering drugs. The Patent Office asserted that a person of ordinary skill in the art would have been motivated to combine orlistat with a bile acid sequestrant because such person would have expected the resulting composition useful in lowering cholesterol.

Applicants' claimed invention has several aspects, including -- a method of treating obesity in an obese patient; a method of reducing the gastrointestinal side effects associated with orlistat treatment; and various pharmaceutical compositions. With regard to the first two aspects of the claimed invention, i.e. the methods of treatment, nowhere does Gregg even hint that a combination of orlistat and a bile acid sequestrant would be useful in treating obesity or reducing the gastrointestinal side effects associated with orlistat treatment. Therefore, applicants' claims directed to these method aspects of the invention cannot be deemed obvious from Gregg.

Turning now to the pharmaceutical composition claims, Gregg discloses the use of an MTP inhibitor in combination with a cholesterol-lowering drug for the purpose of lowering serum lipid levels. As correctly pointed out in the Office Action, Gregg lists among a vast multitude of cholesterol-lowering drugs bile acid sequestrants, such as cholestyramine, colestipol and DEAE-Sephadex, and tetrahydrolipstatin. However, there is no guidance or motivation provided by Gregg to pick and choose among this multitude of exemplified cholesterol lowering drugs. One reading Gregg would have been just as motivated to combine an HMG CoA reductase inhibitor and a squalene synthetase inhibitor or nicotinic acid and aspirin. There is simply no guidance in Gregg that would lead to applicants' claimed combination or suggest the use of this combination for treating obesity or reducing the gastrointestinal side effects associated with orlistat treatment. Gregg provides no teaching or suggestion that applicants' particular combination of orlistat and a bile acid sequestrant would lead to applicants' unexpected finding that unpleasant gastrointestinal side effects encountered using orlistat alone could be reduced or eliminated.

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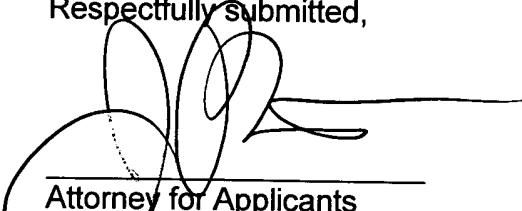
Reconsideration and withdrawal of the rejection under 35 U.S.C. § 103(a) is requested.

In view of the above, applicants request reconsideration and withdrawal of all rejections under 35 U.S.C. § 112 and 103(a). Issuance of a Notice of Allowance is earnestly solicited.

If a telephone conference would be of assistance in furthering prosecution of the subject application, applicants request that the undersigned attorney be contacted at the number below.

No fee, except the fee for a three month extension of time, is required in connection with the filing of this Amendment. If any fees are deemed necessary, authorization is given to charge the amount of any such fee to Deposit Account 08-2525.

Respectfully submitted,



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